K081639

SEP 19 2008

510(K) SUMMARY
Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination

Submitted by: MediCult a/s
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K-30

Contact person: Ronald G. Leonardi, Ph.D.
R&R Registrations
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Date Submitted: June 2, 2008

Device Identification
Trade name: ICSI Cumulase®
Common name: ICSI Cumulase®
Classification name: Reproductive media and supplements (21 CFR 884.6180, Product Code 85 MQL)

Predicate devices:
SynVitro®Cumulase® (K060699) from MediCult a/s and Cumulase® (K042495) from Halozyme.

Description
ICSI Cumulase® is a defined sterile, ready to use media used by professionals within assisted reproduction and intended for the removal of the cumulus complex and corona radiata surrounding the oocyte in preparation for ICSI.
ICSI Cumulase® is a modified version of SynVitro® Cumulase® (K060699) and is based on a salt solution containing a recombinant hyaluronidase and HSA (US license No 1716). ICSI Cumulase® is supplied in transparent polypropylene plastic vials with screw top closures in a volume of 0.5 ml.

Intended use
The removal of the cumulus complex and corona radiata surrounding the oocyte in preparation for ICSI.

Technological Characteristics
The technological characteristics of ICSI Cumulase® are essentially similar to those of the predicate devices. They have the same intended use and contain the recombinant human hyaluronidase enzyme Cumulase®.

Performance data
In order to evaluate the safety and efficiency of ICSI Cumulase® an evaluation of all relevant pre-clinical and clinical literature regarding the use of the Cumulase® enzyme has been performed. The review showed that the product is effective and safe for its intended use.

Product Testing Controls
Each batch is tested according to Ph. Eur. and USP for sterility, osmolality, pH, endotoxin, enzyme activity and Mouse Embryo Assay (MEA). Stability studies have been performed.

Conclusion
It is concluded that the safety and the effectiveness of the product for its intended use is shown in the present submission and that the products are substantially equivalent to the predicate devices MediCult's SynVitro®Cumulase® (K060699) and Halozyme's Cumulase® (K042495).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 19 2008

Medicult a/s
% Ronald G. Leonardi, Ph.D.
President
R & R Registrations
9915 Cam. Chirimolla
SAN DIEGO CALIFORNIA 92131

Re: K081639
Trade Name: ICSI Cumulase®
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: September 3, 2008
Received: September 4, 2008

Dear Dr. Leonardi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

ICSI Cumulase®

Indications For Use:

ICSI Cumulase® is for the removal of the cumulus complex and corona radiata surrounding the oocyte in preparation for ICSI.

Prescription Use __x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K081639